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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/622,199	05/31/01	SCHWARTZ	J P06853US00/L

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HM22/1018

EXAMINER
SEAMAN, D

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 10/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/622,199

Applicant(s)

SCHWARTZ ET AL.

Examiner

D. Margaret Seaman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 39-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 and 79-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-88 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. This application was filed 31 May 2001 and is a 371 of PCT/EP99/05744, filed 29 July 1999. Claims 1-88 are before the Examiner and are subject to the following Lack of Unity.

Election/Restrictions

2. As stated in paper #6, dated 6 September 2001, restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Claims 1-78 are drawn to "Use of". These will be treated as if they were drawn to "A compound of formula_____". Claims 80-88 are drawn to "medicaments". These claims will be treated as if they were drawn to "A method of treating...".

Group I, claim(s) 16-28, drawn to compounds of formula (I).

Group II, claim(s) 29-38 in part, drawn to compounds of formula (IIa).

Group III, claim(s) 29-38 in part, drawn to compounds of formula (IIb).

Group IV, claim(s) 39-42, drawn to compounds of formula (III).

Group V, claim(s) 43-45, drawn to compounds of formula (IV).

Group VI, claim(s) 46-50, drawn to compounds of formula (VI).

Group VII, claim(s) 51-53, drawn to compounds of formula (VII).

Group VIII, claim(s) 54-56, drawn to compounds of formula (VIII).

Group IX, claim(s) 57-58, drawn to compounds of formula (IX).

Group X, claim(s) 59-60, drawn to compounds of formula (X).

Group XI, claim(s) 61-62, drawn to compounds of formula (XI).

Group XII, claim(s) 63-67, drawn to compounds of formula (XII).

Group XIII, claim(s) 68-69, drawn to compounds of formula (XIII).

Group XIV, claim(s) 70-71, drawn to compounds of formula (XIV).

Group XV, claim(s) 72, drawn to compounds of formula (XV).

Group XVI, claim(s) 73, drawn to compounds of formula (XVI).

Group XVII, claim(s) 74, drawn to compounds of formula (XVII).

Group XVIII, claim(s) 75-77, drawn to compounds of formula (V).

Group XIX, claim(s) 1 in part, drawn to compounds other than encompassed in the above groups I-XVIII.

Group XX, claim(s) 78, drawn to a mixture of different active agents of claim 1 and those listed in claim 78, subject to the above lack of unity of invention groups for the compounds of claim 1 plus an election of species for the secondary active ingredient.

37 CFR 1.475. Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features. The expression "special

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technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

3. The inventions listed as Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common core between all of these groups is "N". This is not a special technical feature that forms a technical relationship

among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. However, it is not seen where N is a contribution over the prior art.

4. Applicant's election with traverse of group II in Paper No. 8, dated 9 October 2001, is acknowledged. The traversal is on the ground(s) that the instant claims have unity of invention due to the special technical feature of W. This is not found persuasive because of the following: A common core is something that is the same between all members of the markush grouping. W is defined as a residue which has activity when attached to an imidazole grouping. Well, W is not attached to an imidazole grouping due to the confines of claim 1. There is no teaching in the specification of how to determine if something has activity as a residue. If such is not taught, then it is part of the common knowledge. Common knowledge is not a contribution over the prior art. Therefore, W cannot be a special technical feature.

The requirement is still deemed proper and is therefore made *FINAL*.

5. Claims 39-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8. Claims 1-38 and 78-88 will be examined to the extent that they read upon the elected group II.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-38 and 79-88 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yamada (CA 125:345266), Fenton (CA 125:10758), Psiorz (CA 116:41309) and Witek (CA 89:210420).

Yamada discloses RN 183385-18-4. Fenton discloses RN 154198-28-4. Psiorz discloses RN 138304-40-2. Witek discloses RN 161963-24-2. All of these authors discloses compounds that either make obvious the generic or anticipates the instant claims.

Claim Rejections - 35 USC § 101

4. Claims 1-38 and 79-88 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter, i.e. "Use of" is not a statutory subject matter; however, "A method of using..." or "A compound..." is proper statutory subject matter.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-38 and 79-88 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and/or use the invention. It is not seen where the instant specification enables the ordinary artisan to make/use the instant invention. Examples 66 and 68 differ by a 3-methyl (example 66) and 4-methyl(example 68) and their respective activity is 0.3 and 0.5. Example 59 has R12 being (CH₂)₅ and Example 60 has the same being (CH₂)₆ and their activities are 0.20 and 0.64. Example 43 has n=3 and activity of 0.5 while example 56 has n=4 and activity of 1.1. Example 59 has 4-cyano and activity of 0.02 and example 74 has 4-butyryl and activity of 0.21. These are examples of massive differences in activities with very little difference in structures. The ordinary artisan cannot determine from these examples how to extrapolate to other compounds not specifically made and tested. Also, the specification and the claims state that W is a residue which has activity when attached to imidazole. However, the moiety W is not attached to an imidazole ring in the present claims. So, how can the compound have activity?

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-38 and 79-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims are ambiguous due to the following phrases or their placement in the claim: 1) "residue that imparts activity when attached to an imidazole ring" [What residue? And What imidazole ring?], 2) Are R^{a-d} defined as morpholino and N-substituted piperadino? [Spacing within the claim is ambiguous], 3) "as well as their...", [Indefinite due to the phrasing...are both parts part of the definition or are others preferred?] 4) polymorphic crystalline structures, [Polymorphic how? With their structure?], 5) "R1 and R2 are defined with reference to the general formula previously" [Which general formula previously defined?], 6) "represents" [Should be "selected from"], 7) "it being possible" [Should be "may be selected from"], 8) "such as", "preferably", "in particular" and "more preferably" [Double inclusion within the definition of the moiety.], 9) "Y" as defined previously" [Y" is not previously defined.], 10) "another powerful electronegative group" [This group is not defined.], 11) "denoting" [Vague], 12) "bearing a keto function" [Vague].

The claims are replete with such ambiguous phrases. Correction is required.

Double Patenting

9. Claims 80-88 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 79. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Specification

10. The disclosure is objected to because of the following informalities: Page 152 example 59 has an $ED_{50} = 0,20$. Example 43 has an $ED_{50} = 0.50$. The writing styles are not the same.

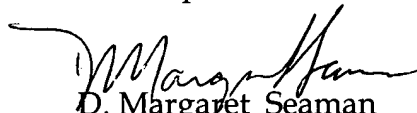
Appropriate correction is required.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 703-308-4528. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on 703-308-2439. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


D. Margaret Seaman
Primary Examiner
Art Unit 1625

dms
October 17, 2001